

AMENDED IN ASSEMBLY JUNE 10, 2014

AMENDED IN SENATE MAY 28, 2013

AMENDED IN SENATE APRIL 23, 2013

AMENDED IN SENATE APRIL 8, 2013

SENATE BILL

No. 600

Introduced by Senator Lieu

February 22, 2013

~~An act to add Section 43006.5 to the Health and Safety Code, relating to vehicular air pollution. An act to amend Sections 4033 and 4045 of, to add Section 2245 to, to repeal Sections 4034, 4034.1, 4163.1, 4163.2, 4163.3, 4163.4, and 4163.5 of, and to repeal and add Section 4163 of, the Business and Professions Code, and to amend Section 111825 of, and to add Section 111397 to, the Health and Safety Code, relating to pharmacy.~~

LEGISLATIVE COUNSEL'S DIGEST

SB 600, as amended, Lieu. ~~Vehicles: alternative fuel. Drugs.~~

(1) Existing federal law, the Federal Food, Drug, and Cosmetic Act, regulates, among other matters, the manufacture, distribution, and sale of prescription drugs in interstate commerce and is administered by the United States Food and Drug Administration.

Existing law, the Medical Practice Act, provides for the licensure and regulation of physicians and surgeons by the Medical Board of California. The act provides that it is unprofessional conduct for a licensee under the act to prescribe, dispense, or furnish dangerous drugs, as defined, under specified circumstances and requires the board to take action against a licensee who is charged with unprofessional

conduct. Under existing law, a violation of any of the enforcement provisions of the act is punishable as a misdemeanor.

This bill would provide that purchasing a foreign dangerous drug or device, illegitimate product, or suspect product that is not approved by the United States Food and Drug Administration or that is obtained outside of the licensed supply chain regulated by the United States Food and Drug Administration, California State Board of Pharmacy, or State Department of Public Health constitutes unprofessional conduct. Because a violation of this provision would be a crime, the bill would impose a state-mandated local program.

(2) Existing law, the federal Drug Supply Chain Security Act establishes the development of a system that will require, among other things, manufacturers, wholesale drug distributors, repackagers, and dispensers in the drug supply chain to provide specified transaction information about a drug product, and prohibits a state or political subdivision of a state from continuing in effect any requirements for tracing products through the distribution system, including any requirements with respect to electronic pedigree systems, that are inconsistent with, more stringent than, or in addition to, any requirements of federal law.

Existing law, the Pharmacy Law, provides for the licensure and regulation of the practice of pharmacy and the sale of dangerous drugs or dangerous devices by the California State Board of Pharmacy. Existing law, commencing July 1, 2016, prohibits a wholesaler or repackager from selling, trading, or transferring a dangerous drug at wholesale without providing a pedigree, as defined, and from acquiring a dangerous drug without receiving a pedigree. Existing law imposes parallel requirements with respect to pharmacies commencing July 1, 2017. Existing law makes these pedigree requirements inoperative upon the effective date of federal law addressing pedigree or serialization measures for dangerous drugs, or as otherwise specified in the event of a conflict with federal law.

This bill would repeal the pedigree requirements and make related conforming changes.

(3) Existing law, the Sherman Food, Drug, and Cosmetic Law, regulates the packaging, labeling, and advertising of drugs and devices and is administered by the State Department of Public Health. Existing law makes it unlawful to manufacture, sell, deliver, hold, or offer for sale, any drug that is misbranded, and provides that a drug or device

is misbranded if its labeling is false or misleading in any particular. A violation of this law is a misdemeanor.

This bill would provide that any foreign dangerous drug that is not approved by the United States Food and Drug Administration or that is obtained outside of the licensed supply chain regulated by the United States Food and Drug Administration, California State Board of Pharmacy, or State Department of Public Health is misbranded. Because a violation of this provision would be a crime, the bill would impose a state-mandated local program.

The bill would provide that any person who purchases a foreign dangerous drug or medical device, or an illegitimate product or suspect product, as those terms are defined pursuant to federal law, that is not approved by the United States Food and Drug Administration or that is obtained outside of the licensed supply chain regulated by the United States Food and Drug Administration, California State Board of Pharmacy, or State Department of Public Health is guilty of a misdemeanor and subject to imprisonment for not more than one year in the county jail, a fine of not more than \$10,000 per occurrence, or both the imprisonment and fine. By creating new crimes, the bill would impose a state-mandated local program.

(4) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

~~Existing law generally designates the State Air Resources Board as the state agency with the primary responsibility for the control of vehicular air pollution. Existing law authorizes the State Air Resources Board to certify the fuel system of any motor vehicle powered by a fuel other than gasoline or diesel if it meets certain standards and to adopt test procedures for that certification.~~

~~This bill, commencing January 1, 2014, would require the state board to use specified procedures for small volume manufacturers of vehicles seeking to have alternative fuel conversion systems certified by the state board. The bill would require the state board, commencing January 1, 2014, to extend the life of a new vehicle or engine certification until December 31 of the year following a given vehicle model year.~~

~~Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no-yes.~~

The people of the State of California do enact as follows:

1 *SECTION 1. Section 2245 is added to the Business and*
2 *Professions Code, to read:*

3 2245. *Purchasing a foreign dangerous drug or device,*
4 *illegitimate product, as defined in Section 360eee(8) of Title 21 of*
5 *the United States Code, or suspect product, as defined in Section*
6 *360eee(21) of Title 21 of the United States Code, that is not*
7 *approved by the United States Food and Drug Administration or*
8 *that is obtained outside of the licensed supply chain regulated by*
9 *the United States Food and Drug Administration, California State*
10 *Board of Pharmacy, or State Department of Public Health*
11 *constitutes unprofessional conduct.*

12 *SEC. 2. Section 4033 of the Business and Professions Code is*
13 *amended to read:*

14 4033. (a) (1) “Manufacturer” means and includes every person
15 who prepares, derives, produces, compounds, or repackages any
16 drug or device except a pharmacy that manufactures on the
17 immediate premises where the drug or device is sold to the ultimate
18 consumer.

19 (2) Notwithstanding paragraph (1), “manufacturer” shall not
20 mean a pharmacy compounding a drug for parenteral therapy,
21 pursuant to a prescription, for delivery to another pharmacy for
22 the purpose of delivering or administering the drug to the patient
23 or patients named in the prescription, provided that neither the
24 components for the drug nor the drug are compounded, fabricated,
25 packaged, or otherwise prepared prior to receipt of the prescription.

26 (3) Notwithstanding paragraph (1), “manufacturer” shall not
27 mean a pharmacy that, at a patient’s request, repackages a drug
28 previously dispensed to the patient, or to the patient’s agent,
29 pursuant to a prescription.

30 (b) Notwithstanding subdivision (a), ~~as used in Sections 4034,~~
31 ~~4163, 4163.1, 4163.2, 4163.3, 4163.4, and 4163.5,~~ “manufacturer”
32 *also* means a person who prepares, derives, manufactures,
33 produces, or repackages a dangerous drug, as defined in Section
34 4022, device, or cosmetic. Manufacturer also means the holder or
35 holders of a New Drug Application (NDA), an Abbreviated New
36 Drug Application (ANDA), or a Biologics License Application
37 (BLA), provided that such application has been approved; a
38 manufacturer’s third party logistics provider; a private label

1 distributor (including colicensed partners) for whom the private
2 label distributor's prescription drugs are originally manufactured
3 and labeled for the distributor and have not been repackaged; or
4 the distributor agent for the manufacturer, contract manufacturer,
5 or private label distributor, whether the establishment is a member
6 of the manufacturer's affiliated group (regardless of whether the
7 member takes title to the drug) or is a contract distributor site.

8 *SEC. 3. Section 4034 of the Business and Professions Code is*
9 *repealed.*

10 ~~4034. (a) "Pedigree" means a record, in electronic form,~~
11 ~~containing information regarding each transaction resulting in a~~
12 ~~change of ownership of a given dangerous drug, from sale by a~~
13 ~~manufacturer, through acquisition and sale by one or more~~
14 ~~wholesalers, manufacturers, repackagers, or pharmacies, until final~~
15 ~~sale to a pharmacy or other person furnishing, administering, or~~
16 ~~dispensing the dangerous drug. The pedigree shall be created and~~
17 ~~maintained in an interoperable electronic system, ensuring~~
18 ~~compatibility throughout all stages of distribution.~~

19 ~~(b) A pedigree shall include all of the following information:~~

20 ~~(1) The source of the dangerous drug, including the name, the~~
21 ~~federal manufacturer's registration number or a state license~~
22 ~~number as determined by the board, and principal address of the~~
23 ~~source.~~

24 ~~(2) The trade or generic name of the dangerous drug, the quantity~~
25 ~~of the dangerous drug, its dosage form and strength, the date of~~
26 ~~the transaction, the sales invoice number or, if not immediately~~
27 ~~available, a customer-specific shipping reference number linked~~
28 ~~to the sales invoice number, the container size, the number of~~
29 ~~containers, the expiration dates, and the lot numbers.~~

30 ~~(3) The business name, address, and the federal manufacturer's~~
31 ~~registration number or a state license number as determined by the~~
32 ~~board, of each owner of the dangerous drug, and the dangerous~~
33 ~~drug shipping information, including the name and address of each~~
34 ~~person certifying delivery or receipt of the dangerous drug.~~

35 ~~(4) A certification under penalty of perjury from a responsible~~
36 ~~party of the source of the dangerous drug that the information~~
37 ~~contained in the pedigree is true and accurate.~~

38 ~~(5) The unique identification number described in subdivision~~
39 ~~(i).~~

~~(c) A single pedigree shall include every change of ownership of a given dangerous drug from its initial manufacture through to its final transaction to a pharmacy or other person for furnishing, administering, or dispensing the drug, regardless of repackaging or assignment of another National Drug Code (NDC) Directory number. Dangerous drugs that are repackaged shall be serialized by the repackager and a pedigree shall be provided that references the pedigree of the original package or packages provided by the manufacturer.~~

~~(d) A pedigree shall track each dangerous drug at the smallest package or immediate container distributed by the manufacturer, received and distributed by the wholesaler or repackager, and received by the pharmacy or another person furnishing, administering, or dispensing the dangerous drug. For purposes of this section, the “smallest package or immediate container” of a dangerous drug shall include any dangerous drug package or container made available to a repackager, wholesaler, pharmacy, or other entity for repackaging or redistribution, as well as the smallest unit made by the manufacturer for sale to the pharmacy or other person furnishing, administering, or dispensing the drug.~~

~~(e) Any return of a dangerous drug to a wholesaler or manufacturer shall be documented on the same pedigree as the transaction that resulted in the receipt of the drug by the party returning it.~~

~~(f) If a licensed health care service plan, hospital organization, and one or more physician organizations have exclusive contractual relationships to provide health care services, drugs distributed between these persons shall be deemed not to have changed ownership.~~

~~(g) The following transactions are exempt from the pedigree requirement created by this section:~~

~~(1) An intracompany sale or transfer of a dangerous drug. For purposes of this section, “intracompany sale or transfer” means any transaction for any valid business purpose between a division, subsidiary, parent, or affiliated or related company under the common ownership and control of the same corporate or legal entity.~~

~~(2) Dangerous drugs received by the state or a local government entity from a department or agency of the federal government or~~

1 ~~an agent of the federal government specifically authorized to~~
2 ~~deliver dangerous drugs to the state or local government entity.~~

3 ~~(3) The provision of samples of dangerous drugs by a~~
4 ~~manufacturer's employee to an authorized prescriber, provided~~
5 ~~the samples are dispensed to a patient of the prescriber without~~
6 ~~charge.~~

7 ~~(4) (A) A sale, trade, or transfer of a radioactive drug, as defined~~
8 ~~in Section 1708.3 of Title 16 of the California Code of Regulations;~~
9 ~~between any two entities licensed by the Radiologic Health Branch~~
10 ~~of the State Department of Public Health, the federal Nuclear~~
11 ~~Regulatory Commission, or an Agreement state.~~

12 ~~(B) The exemption in this paragraph shall remain in effect unless~~
13 ~~the board, no earlier than the date that is two years after the~~
14 ~~compliance date for manufacturers set forth in subdivision (k) of~~
15 ~~Section 4034 or Section 4163.5, determines after consultation with~~
16 ~~the Radiologic Health Branch of the State Department of Public~~
17 ~~Health that the risk of counterfeiting or diversion of a radioactive~~
18 ~~drug is sufficient to require a pedigree. Two years following the~~
19 ~~date of any such determination, this paragraph shall become~~
20 ~~inoperative.~~

21 ~~(5) The sale, trade, or transfer of a dangerous drug that is labeled~~
22 ~~by the manufacturer as "for veterinary use only."~~

23 ~~(6) The sale, trade, or transfer of compressed medical gas. For~~
24 ~~purposes of this section, "compressed medical gas" means any~~
25 ~~substance in its gaseous or cryogenic liquid form that meets~~
26 ~~medical purity standards and has application in a medical or~~
27 ~~homecare environment, including, but not limited to, oxygen and~~
28 ~~nitrous oxide.~~

29 ~~(7) The sale, trade, or transfer of solutions. For purposes of this~~
30 ~~section, "solutions" means any of the following:~~

31 ~~(A) Those intravenous products that, by their formulation, are~~
32 ~~intended for the replenishment of fluids and electrolytes, such as~~
33 ~~sodium, chloride, and potassium, calories, such as dextrose and~~
34 ~~amino acids, or both.~~

35 ~~(B) Those intravenous products used to maintain the equilibrium~~
36 ~~of water and minerals in the body, such as dialysis solutions.~~

37 ~~(C) Products that are intended for irrigation or reconstitution,~~
38 ~~as well as sterile water, whether intended for those purposes or for~~
39 ~~injection.~~

~~(8) Dangerous drugs that are placed in a sealed package with a medical device or medical supplies at the point of first shipment into commerce by the manufacturer and the package remains sealed until the drug and device are used, provided that the package is only used for surgical purposes.~~

~~(9) A product that meets either of the following criteria:~~

~~(A) A product comprised of two or more regulated components, such as a drug/device, biologic/device, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity.~~

~~(B) Two or more separate products packaged together in a single package or as a unit and comprised of drug and device products or device and biological products.~~

~~(h) If a manufacturer, wholesaler, or pharmacy has reasonable cause to believe that a dangerous drug in, or having been in, its possession is counterfeit or the subject of a fraudulent transaction, the manufacturer, wholesaler, or pharmacy shall notify the board within 72 hours of obtaining that knowledge. This subdivision shall apply to any dangerous drug that has been sold or distributed in or through this state.~~

~~(i) “Interoperable electronic system” as used in this chapter means an electronic track and trace system for dangerous drugs that uses a unique identification number, established at the point of manufacture and supplemented by a linked unique identification number in the event that drug is repackaged, contained within a standardized nonproprietary data format and architecture, that is uniformly used by manufacturers, wholesalers, repackagers, and pharmacies for the pedigree of a dangerous drug. No particular data carrier or other technology is mandated to accomplish the attachment of the unique identification number described in this subdivision.~~

~~(j) The application of the pedigree requirement shall be subject to review during the board’s evaluation pursuant to Section 473.4.~~

~~(k) This section shall become operative on January 1, 2015.~~

SEC. 4. Section 4034.1 of the Business and Professions Code is repealed.

~~4034.1. (a) (1) Upon the effective date of federal legislation or adoption of a federal regulation addressing pedigree or serialization measures for dangerous drugs, Sections 4034, 4163, 4163.1, 4163.2, 4163.4, and 4163.5 shall become inoperative.~~

1 ~~(2) Within 90 days of the enactment of federal legislation or~~
2 ~~adoption of a regulation addressing pedigree or serialization~~
3 ~~measures for dangerous drugs, the board shall publish a notice that~~
4 ~~Sections 4034, 4163, 4163.1, 4163.2, 4163.4, and 4163.5 are~~
5 ~~inoperative.~~

6 ~~(3) Within 90 days of the enactment of federal legislation or~~
7 ~~adoption of a regulation that is inconsistent with any provision of~~
8 ~~California law governing the application of any pedigree or~~
9 ~~serialization requirement or standard, the board shall adopt~~
10 ~~emergency regulations necessary to reflect the inoperation of state~~
11 ~~law.~~

12 ~~(b) (1) If the Food and Drug Administration (FDA) enacts any~~
13 ~~rule, standard, or takes any other action that is inconsistent with~~
14 ~~any provision of California law governing application of a pedigree~~
15 ~~to a dangerous drug, that provision of California law shall be~~
16 ~~inoperative.~~

17 ~~(2) Within 90 days of the FDA enacting any rule, standard, or~~
18 ~~taking any other action that is inconsistent with any provision of~~
19 ~~California law governing application of a pedigree to a dangerous~~
20 ~~drug, the board shall publish a notice that the provision is~~
21 ~~inoperative.~~

22 ~~(3) Within 90 days of the FDA enacting any rule, standard, or~~
23 ~~taking any other action that is inconsistent with any provision of~~
24 ~~California law governing application of a pedigree to a dangerous~~
25 ~~drug, the board shall adopt emergency regulations necessary to~~
26 ~~reflect the inoperation of state law.~~

27 ~~(e) If the board fails to recognize the inoperation within 90 days~~
28 ~~pursuant to this section, nothing in this section shall preclude a~~
29 ~~party from filing an action in state or federal court for declaratory~~
30 ~~or injunctive relief as an alternative to filing a petition with the~~
31 ~~board.~~

32 ~~SEC. 5. Section 4045 of the Business and Professions Code is~~
33 ~~amended to read:~~

34 4045. “Third-party logistics provider” or “reverse third-party
35 logistic provider” means an entity licensed as a wholesaler that
36 contracts with a dangerous drug manufacturer to provide or
37 coordinate warehousing, distribution, or other similar services on
38 behalf of a manufacturer, but for which there is no change of
39 ownership in the dangerous drugs. ~~For purposes of Sections 4034,~~
40 ~~4163, 4163.1, 4163.2, 4163.3, 4163.4, and 4163.5, a third-party~~

1 ~~logistics provider shall not be responsible for generating or~~
2 ~~updating pedigree documentation, but shall maintain copies of the~~
3 ~~pedigree. To be exempt from documentation for pedigrees, a~~
4 ~~reverse third-party logistic provider may only accept~~
5 ~~decommissioned drugs from pharmacies or wholesalers.~~

6 *SEC. 6. Section 4163 of the Business and Professions Code is*
7 *repealed.*

8 ~~4163. (a) A manufacturer, wholesaler, repackager, or pharmacy~~
9 ~~may not furnish a dangerous drug or dangerous device to an~~
10 ~~unauthorized person.~~

11 ~~(b) Dangerous drugs or dangerous devices shall be acquired~~
12 ~~from a person authorized by law to possess or furnish dangerous~~
13 ~~drugs or dangerous devices. When the person acquiring the~~
14 ~~dangerous drugs or dangerous devices is a wholesaler, the~~
15 ~~obligation of the wholesaler shall be limited to obtaining~~
16 ~~confirmation of licensure of those sources from whom it has not~~
17 ~~previously acquired dangerous drugs or dangerous devices.~~

18 ~~(c) Except as otherwise provided in Section 4163.5, commencing~~
19 ~~on July 1, 2016, a wholesaler or repackager may not sell, trade, or~~
20 ~~transfer a dangerous drug at wholesale without providing a~~
21 ~~pedigree.~~

22 ~~(d) Except as otherwise provided in Section 4163.5, commencing~~
23 ~~on July 1, 2016, a wholesaler or repackager may not acquire a~~
24 ~~dangerous drug without receiving a pedigree.~~

25 ~~(e) Except as otherwise provided in Section 4163.5, commencing~~
26 ~~on July 1, 2017, a pharmacy may not sell, trade, or transfer a~~
27 ~~dangerous drug at wholesale without providing a pedigree.~~

28 ~~(f) Except as otherwise provided in Section 4163.5, commencing~~
29 ~~on July 1, 2017, a pharmacy may not acquire a dangerous drug~~
30 ~~without receiving a pedigree.~~

31 ~~(g) Except as otherwise provided in Section 4163.5, commencing~~
32 ~~on July 1, 2017, a pharmacy warehouse may not acquire a~~
33 ~~dangerous drug without receiving a pedigree. For purposes of this~~
34 ~~section and Section 4034, a “pharmacy warehouse” means a~~
35 ~~physical location licensed as a wholesaler for prescription drugs~~
36 ~~that acts as a central warehouse and performs intracompany sales~~
37 ~~or transfers of those drugs to a group of pharmacies under common~~
38 ~~ownership and control.~~

39 *SEC. 7. Section 4163 is added to the Business and Professions*
40 *Code, to read:*

1 4163. (a) A manufacturer, wholesaler, repackager, or
2 pharmacy may not furnish a dangerous drug or dangerous device
3 to an unauthorized person.

4 (b) Dangerous drugs or dangerous devices shall be acquired
5 from a person authorized by law to possess or furnish dangerous
6 drugs or dangerous devices. When the person acquiring the
7 dangerous drugs or dangerous devices is a wholesaler, the
8 obligation of the wholesaler shall be limited to obtaining
9 confirmation of licensure of those sources from whom it has not
10 previously acquired dangerous drugs or dangerous devices.

11 SEC. 8. Section 4163.1 of the Business and Professions Code,
12 as added by Section 68 of Chapter 658 of the Statutes of 2006, is
13 repealed.

14 ~~4163.1. It is the intent of the Legislature that commencing on~~
15 ~~January 1, 2007, and continuing through the full implementation~~
16 ~~of the pedigree requirements specified by Section 4163,~~
17 ~~manufacturers and wholesalers shall use best efforts to provide in~~
18 ~~the most readily accessible form possible, information regarding~~
19 ~~the manufacturer's specific relationships in the distribution of~~
20 ~~dangerous drugs with wholesalers.~~

21 SEC. 9. Section 4163.1 of the Business and Professions Code,
22 as added by Section 9 of Chapter 713 of the Statutes of 2008, is
23 repealed.

24 ~~4163.1. (a) For purposes of Sections 4034 and 4163, "drop~~
25 ~~shipment" means a sale of a dangerous drug by the manufacturer~~
26 ~~of the dangerous drug whereby all of the following occur:~~

27 ~~(1) The pharmacy, or other person authorized by law to dispense~~
28 ~~or administer the drug, receives delivery of the dangerous drug~~
29 ~~directly from the manufacturer.~~

30 ~~(2) The wholesale distributor takes ownership of, but not~~
31 ~~physical possession of, the dangerous drug.~~

32 ~~(3) The wholesale distributor invoices the pharmacy or other~~
33 ~~person authorized by law to dispense or administer the drug in~~
34 ~~place of the manufacturer.~~

35 ~~(b) The board may develop regulations to establish an alternative~~
36 ~~process to convey the pedigree information required in Section~~
37 ~~4034 for dangerous drugs that are sold by drop shipment.~~

38 SEC. 10. Section 4163.2 of the Business and Professions Code
39 is repealed.

1 ~~4163.2.—(a) (1) A manufacturer, wholesaler, or pharmacy~~
2 ~~lawfully possessing or owning dangerous drugs manufactured or~~
3 ~~distributed prior to the operative date of the pedigree requirements,~~
4 ~~specified in Sections 4034 and 4163, may designate these~~
5 ~~dangerous drugs as not subject to the pedigree requirements by~~
6 ~~preparing a written declaration made under penalty of perjury that~~
7 ~~lists those dangerous drugs.~~

8 ~~(2) The written declaration shall include the National Drug Code~~
9 ~~Directory lot number for each dangerous drug designated. The~~
10 ~~written declaration shall be submitted to and received by the board~~
11 ~~no later than 30 days after the operative date of the pedigree~~
12 ~~requirements. The entity or person submitting the written~~
13 ~~declaration shall also retain for a period of three years and make~~
14 ~~available for inspection by the board a copy of each written~~
15 ~~declaration submitted.~~

16 ~~(3) The board may, by regulation, further specify the~~
17 ~~requirements and procedures for the creation and submission of~~
18 ~~these written declarations. Information contained in these~~
19 ~~declarations shall be considered trade secrets and kept confidential~~
20 ~~by the board.~~

21 ~~(b) Any dangerous drugs designated on a written declaration~~
22 ~~timely created and submitted to the board may be purchased, sold,~~
23 ~~acquired, returned, or otherwise transferred without meeting the~~
24 ~~pedigree requirements, if the transfer complies with the other~~
25 ~~requirements of this chapter.~~

26 ~~SEC. 11. Section 4163.3 of the Business and Professions Code~~
27 ~~is repealed.~~

28 ~~4163.3.—(a) It is the intent of the Legislature that participants~~
29 ~~in the distribution chain for dangerous drugs, including~~
30 ~~manufacturers, wholesalers, or pharmacies furnishing,~~
31 ~~administering, or dispensing dangerous drugs, distribute and~~
32 ~~receive electronic pedigrees, and verify and validate the delivery~~
33 ~~and receipt of dangerous drugs against those pedigrees at the unit~~
34 ~~level, in a manner that maintains the integrity of the pedigree~~
35 ~~system without an unacceptable increase in the risk of diversion~~
36 ~~or counterfeiting.~~

37 ~~(b) To meet this goal, and to facilitate efficiency and safety in~~
38 ~~the distribution chain, the board shall, by regulation, define the~~
39 ~~circumstances under which participants in the distribution chain~~
40 ~~may infer the contents of a case, pallet, or other aggregate of~~

1 individual units, packages, or containers of dangerous drugs, from
2 a unique identifier associated with the case, pallet, or other
3 aggregate, without opening each case, pallet, or other aggregate
4 or otherwise individually validating each unit.

5 (e) ~~Manufacturers, wholesalers, and pharmacies opting to~~
6 ~~employ the use of inference as authorized by the board to comply~~
7 ~~with the pedigree requirements shall document their processes and~~
8 ~~procedures in their standard operating procedures (SOPs) and shall~~
9 ~~make those SOPs available for board review.~~

10 (d) ~~SOPs regarding inference shall include a process for~~
11 ~~statistically sampling the accuracy of information sent with inbound~~
12 ~~product.~~

13 (e) ~~Liability associated with accuracy of product information~~
14 ~~and pedigree using inference shall be specified in the board's~~
15 ~~regulations.~~

16 *SEC. 12. Section 4163.4 of the Business and Professions Code*
17 *is repealed.*

18 ~~4163.4. (a) All units of dangerous drug in the possession of a~~
19 ~~wholesaler or pharmacy, for which the manufacturer does not hold~~
20 ~~legal title on the effective date of the pedigree requirement set~~
21 ~~forth in Section 4163.5, shall not be subject to the pedigree~~
22 ~~requirements set forth in Sections 4034 and 4163. However, if any~~
23 ~~units of those drugs are subsequently returned to the manufacturer,~~
24 ~~they shall be subject to the pedigree requirements if the~~
25 ~~manufacturer distributes those units in California.~~

26 (b) ~~All units of dangerous drug manufactured in California but~~
27 ~~distributed outside the state for dispensing outside the state shall~~
28 ~~not be subject to the pedigree requirements set forth in Sections~~
29 ~~4034 and 4163 at either the time of initial distribution or in the~~
30 ~~event that any of those units are subsequently returned to the~~
31 ~~manufacturer.~~

32 *SEC. 13. Section 4163.5 of the Business and Professions Code*
33 *is repealed.*

34 ~~4163.5. (a) The Legislature hereby finds and declares that:~~

35 (1) ~~The electronic pedigree system required by Sections 4034~~
36 ~~and 4163 will provide tremendous benefits to the public and to all~~
37 ~~participants in the distribution chain. Those benefits should be~~
38 ~~made available as quickly as possible through the full cooperation~~
39 ~~of prescription drug supply chain participants. To this end, all drug~~
40 ~~manufacturers and repackagers are strongly encouraged to serialize~~

1 drug products and initiate electronic pedigrees as soon as possible;
2 and all participants in the supply chain are encouraged to
3 immediately ready themselves to receive and pass electronic
4 pedigrees.

5 (2) At the same time, it is recognized that the process of
6 implementing serialized electronic pedigree for all prescription
7 drugs in the entire chain of distribution is a complicated
8 technological and logistical undertaking for manufacturers,
9 wholesalers, repackagers, pharmacies, and other supply chain
10 participants. The Legislature seeks to ensure continued availability
11 of prescription drugs in California while participants implement
12 these requirements.

13 (b) Before January 1, 2015, each manufacturer of a dangerous
14 drug distributed in California shall designate those dangerous drugs
15 representing a minimum of 50 percent of its drugs, generic or
16 single source, distributed in California, for which it is listed as the
17 manufacturer by the federal Food and Drug Administration, which
18 shall be the subject of its initial phase of compliance with the
19 January 1, 2015, deadline of the state's serialized electronic
20 pedigree requirements set forth in Sections 4034 and 4163. Each
21 manufacturer shall notify the Board of Pharmacy of the drugs so
22 designated and the measure or measures used in designating its
23 drugs to be serialized, and shall include in the notification the
24 technology to be used to meet the serialized electronic pedigree
25 requirements. The notification process for these specific actions
26 may be specified by the board.

27 (c) Before January 1, 2016, each manufacturer of a dangerous
28 drug distributed in California shall designate the final 50 percent
29 of its drugs, generic or single source, distributed in California for
30 which it is listed as the manufacturer by the federal Food and Drug
31 Administration that are subject to the state's serialized electronic
32 pedigree requirements set forth in Sections 4034 and 4163, which
33 shall comply with the state's serialized electronic pedigree
34 requirement by January 1, 2016. Each manufacturer shall notify
35 the Board of Pharmacy of the drugs so designated and the measure
36 or measures used in designating its drugs to be serialized, and shall
37 include in the notification the technology to be used to meet the
38 serialized electronic pedigree requirements. The notification
39 process for these specific actions may be specified by the board.

1 ~~(d) For purposes of designating drugs to be serialized as required~~
2 ~~by subdivisions (b) and (c), manufacturers shall select from any~~
3 ~~of the following measures:~~

4 ~~(1) Unit volume.~~

5 ~~(2) Product package (SKU) type.~~

6 ~~(3) Drug product family.~~

7 ~~(e) Drugs not subject to compliance with the pedigree~~
8 ~~requirements set forth in Sections 4034 and 4163 under this section~~
9 ~~shall not be subject to the provisions of subdivisions (c), (d), (e),~~
10 ~~and (f) of Section 4163.~~

11 *SEC. 14. Section 111397 is added to the Health and Safety*
12 *Code, to read:*

13 *111397. Any foreign dangerous drug that is not approved by*
14 *the United States Food and Drug Administration or that is obtained*
15 *outside of the licensed supply chain regulated by the United States*
16 *Food and Drug Administration, California State Board of*
17 *Pharmacy, or State Department of Public Health is misbranded.*

18 *SEC. 15. Section 111825 of the Health and Safety Code is*
19 *amended to read:*

20 *111825. (a) Any person who violates any provision of this*
21 *part or any regulation adopted pursuant to this part shall, if*
22 *convicted, be subject to imprisonment for not more than one year*
23 *in the county jail or a fine of not more than one thousand dollars*
24 *(\$1,000), or both the imprisonment and fine.*

25 *(b) Notwithstanding subdivision (a), any person who violates*
26 *Section 111865 by removing, selling, or disposing of an embargoed*
27 *food, drug, device, or cosmetic without the permission of an*
28 *authorized agent of the department or court shall, if convicted, be*
29 *subject to imprisonment for not more than one year in the county*
30 *jail or a fine of not more than ten thousand dollars (\$10,000), or*
31 *both the fine and imprisonment.*

32 *(c) Notwithstanding subdivision (a), any person who purchases*
33 *a foreign dangerous drug or medical device, illegitimate product,*
34 *as defined in Section 360eee(8) of Title 21 of the United States*
35 *Code, or suspect product, as defined in Section 360eee(21) of Title*
36 *21 of the United States Code, that is not approved by the United*
37 *States Food and Drug Administration or that is obtained outside*
38 *of the licensed supply chain regulated by the United States Food*
39 *and Drug Administration, California State Board of Pharmacy,*
40 *or State Department of Public Health is guilty of a misdemeanor*

1 *and subject to imprisonment for not more than one year in the*
2 *county jail, a fine of not more than ten thousand dollars (\$10,000)*
3 *per occurrence, or both the imprisonment and fine.*

4 (e)

5 (d) If the violation is committed after a previous conviction
6 under this section that has become final, or if the violation is
7 committed with intent to defraud or mislead, or if the person
8 committed a violation of Section 110625 or 111300 that was
9 intentional or that was intended to cause injury, the person shall
10 be subject to imprisonment for not more than one year in the county
11 jail, imprisonment in state prison, or a fine of not more than ten
12 thousand dollars (\$10,000), or both the imprisonment and fine.

13 *SEC. 16. No reimbursement is required by this act pursuant*
14 *to Section 6 of Article XIII B of the California Constitution because*
15 *the only costs that may be incurred by a local agency or school*
16 *district will be incurred because this act creates a new crime or*
17 *infraction, eliminates a crime or infraction, or changes the penalty*
18 *for a crime or infraction, within the meaning of Section 17556 of*
19 *the Government Code, or changes the definition of a crime within*
20 *the meaning of Section 6 of Article XIII B of the California*
21 *Constitution.*

22 ~~SECTION 1. Section 43006.5 is added to the Health and Safety~~
23 ~~Code, to read:~~

24 ~~43006.5. (a) Commencing January 1, 2014, for purposes of~~
25 ~~small volume manufacturers of vehicles seeking to have alternative~~
26 ~~fuel conversion systems certified by the state board, the state board~~
27 ~~shall do all of the following:~~

28 ~~(1) Automatically qualify new vehicle alternative fuel~~
29 ~~conversion certifications for aftermarket certifications if requested.~~
30 ~~Requests may be made with a one-page letter and additional~~
31 ~~documentation necessary for labeling and warranty.~~

32 ~~(2) Use commercially available fuel for all required emissions~~
33 ~~testing.~~

34 ~~(3) Conduct evaporative emissions testing only on the added~~
35 ~~alternative fuel system when seeking to certify a dual-fuel vehicle~~
36 ~~conversion.~~

37 ~~(b) Commencing January 1, 2014, the state board shall extend~~
38 ~~the life of a new vehicle or engine certification until December 31~~
39 ~~of the year following a given vehicle model year.~~

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